K071257 pg 1 of 2

SECTION 2 – 510(k) SUMMARY *revised 6/13/07*

MINILOK QuickAnchor Plus with Orthocord
Mini QuickAnchor Plus with Orthocord

JUN 29 2007

Submitter's Name and Address:	DePuy Mitek a Johnson & Johnson company 325 Paramount Drive Raynham, MA 02767
Contact Person	Kristine Christo Senior Regulatory Affairs Associate DePuy Mitek a Johnson & Johnson company 325 Paramount Drive Raynham, MA 02767 Telephone: 508 828-3359 Facsimile: 508 977-6911 e-mail: KChristo@Dpyus.jnj.com
Name of Medical Device	Classification Name: Fastener, Fixation, Biodegradable, Soft Tissue Common/Usual Name: Bone Anchor Proprietary Name: MINILOK QuickAnchor Plus Classification Name: Smooth or threaded metallic bone fixation fastener Common/Usual Name: Bone Anchor Proprietary Name: Mini QuickAnchor Plus Classification Name: Absorbable PDS suture, nonabsorbable polyethylene suture Common/Usual Name: Suture Proprietary Name: Orthocord Suture
Substantial Equivalence	MINI QuickAnchor Plus w/ Orthocord, MINILOK QuickAnchor w/ Orthocord, and Orthocord Suture size 2-0, are substantially equivalent to: Mini QuickAnchor Plus (K930892, K992487 and K992623); MINILOK QuickAnchor Plus (K030995); and Orthocord Suture Size 2 (K043298, K04004) manufactured by DePuy Mitek.
Device Classification	Bone anchors/screws are classified by FDA as a Class II Medical Devices under the generic categories of Single/Multiple Component Metallic Bone Fixation Appliances, Orthopedic Devices Panel (reference 21 CFR §888.3030). Product code MAI. , Smooth or threaded metallic fastener (reference 21 CFR §888.3040)

	Product code: HWC Sutures are classified by the FDA as Class II Medical Devices under the category of absorbable polydioxanone surgical suture(reference 21 CFR §878.4840) Product code:NEW, GAT
Device Description	The MiniQuick Anchor Plus w/ Orthocord, and MINILOK QuickAnchor w/ Orthocord, are preloaded disposable anchor/inserter assemblies designed to facilitate the delivery and installation of the anchor into bone.
Proposed Indications for Use	The MINI QuickAnchor Plus is indicated for use in soft tissue to bone fixation in association with adequate postoperative immobilization as follows: Shoulder: Bankart Repair Wrist: Scapholunate ligament reconstruction. Hand: Thumb ulnar or radial collateral ligament. Foot: Hallux valgus reconstruction. Ankle: Midfoot reconstruction. The MINILOK QuickAnchor Plus is indicated for use in soft tissue to bone fixation in association with adequate postoperative immobilization as follows: Wrist: Scapholunate ligament reconstruction. Hand: Thumb ulnar or radial collateral ligament. Foot: Hallux valgus reconstruction. Ankle: Midfoot reconstruction.
Safety	Biocompatibility studies have demonstrated the MiniQuick Anchor Plus w/ Orthocord, MINILOK QuickAnchor w/ Orthocord, to be non-toxic, non-irritating, non-sensitizing, and non-cytotoxic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DePuy Mitek
a Johnson & Johnson company
% Ms. Kristine Christo
Senior Regulatory Affairs Associate
325 Paramount Drive
Raynham, Massachusetts 02767

JUN 29 2007

Re: K071257
Trade/Device Name: MINILOK QuickAnchor Plus with Orthocord
Mini QuickAnchor Plus with Orthocord
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic
bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: JDR, HWC, MAI
Dated: May 3, 2007
Received: May 4, 2007

Dear Ms. Christo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or 240-276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE revised 6/13/07

510(k) Number (if known): K071257

Device Name(s): MINILOK QuickAnchor Plus w/ Orthocord

Indications for Use:

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Wrist: Scapholunate ligament reconstruction.
Hand: Thumb ulnar or radial collateral ligament.
Foot: Hallux valgus reconstruction.
Ankle: Midfoot reconstruction.

Prescription Use ___x___ or Over-the-Counter Use ___ND___

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071257

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)